



DEPARTMENT OF HEALTH AND HUMAN SERVICE

34566.1
Southwest Region

Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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December 31, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jesper Johansen
Owner/Manager
Aqua Micron LLC
7220 South Fraser Street
Centennial, CO 80112

Ref. # DEN- 04-03

Dear Mr. Johansen:

On August 28 – September 8, 2003 Investigator Michael J. Kuchta of our office conducted an inspection of Aqua Micron LLC, Centennial, CO. This inspection found significant deviations from FDA's regulations establishing current good manufacturing practices (cGMPs) for finished pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Such deviations cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under Section 201(g)(1)(B) of the Act, drugs are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Our investigator determined that your firm manufactures various sanitizing teat dips and teat dip concentrates. Because your cow teat dips are intended for use in controlling mastitis in cows, they are drugs under the Act.

Under Section 501(a)(2)(B) of the Act, if the methods used in, or the facilities or controls used for, a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice, the drug is deemed adulterated. Deviations noted during the inspection of your facility included:

1. Master production and control records lack complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed as required by 21 CFR 211.186(b)(9).

2. Batch production and control records for each batch of drug product produced do not include an accurate reproduction of the appropriate master production or control record which was checked for accuracy, dated and signed as required by 21 CFR 211.188(a).
3. Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity as required by 21 CFR 211.160(b).
4. Written procedures are lacking which describe in sufficient detail the handling, sampling, testing, and approval or rejection of components and drug product containers and closures as required by 21 CFR 211.80(a).
5. Records fail to include an individual inventory record of each component with sufficient information to allow determination of any batch or lot of drug product associated with the use of each component as required by 21 CFR 211.184(c).
6. The drug product is not identified with a lot or control number that permits determination of the history of the manufacture and control of the batch as required by 21 CFR 211.130(c).
7. Distribution records do not contain the lot or control number of drug product as required by 21 CFR 211.196.
8. There is no written testing program designed to assess the stability characteristics of drug products as required by 21 CFR 211.166(a).
9. Reserve samples that are representative of each lot in each shipment of each active ingredient are not retained for one year after the expiration date of the last lot of the drug product containing the active ingredient as required by 21 CFR 211.170(a)(1).
10. Reserve samples that are representative of each lot or batch of drug product are not retained and stored under conditions consistent with product labeling for one year after the expiration date of the drug product as required by 21 CFR 211.170(b)(1).
11. Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing; or holding of a drug product as required by 21 CFR 211.67(b).
12. Procedures describing the handling of all written and oral complaints regarding a drug product are not established as required by 21 CFR 211.198(a).

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with the requirements of the law.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken or will take to correct the deficiencies and prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and a deadline by which the corrections will be completed. Your response should be directed to H. Tom Warwick, Compliance Officer, at the above address:

Sincerely,

Howard E. Monahan, ADD for

B. Belinda Collins
District Director